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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,140	10/31/2005	Eva Kontsekova	SONN:065US	5448

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
11/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,140	KONTSEKOVA, EVA	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,40 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39,40 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 39-40 and 43-46 are pending for examination.

Claim Rejections - 35 USC § 112

2. Claims 39-40 remain rejected and claims 43-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making a transgenic mouse and rat comprising a genome having a double truncated tau sequence integrated therein, does not reasonably provide enablement for making a transgenic animal of *any* species, wherein the genome of said animal comprises a double truncated tau sequence integrated into the endogenous tau equivalent gene of said any species of animal, and further wherein said animal exhibits Alzheimer's disease associated risk factors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. Applicant's arguments filed 08/03/09 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the current claims overcome each of the issues identified in the Action. According to Applicants, the amendment of the claims to recite a description of the double truncation, has been rewritten in independent form, and are directed to transgenic rats and mice. Moreover, Applicants argue that the claims have been amended to recite a tissue specific promoter that would drive expression in relevant cells. Furthermore, Applicants argue that the Action acknowledges that tissue-specific promoters were known in the art.

4. As stated in the prior Office Action, Applicants do not describe the particular constructs comprising a tissue specific promoter used to produce the transgenic animals encompassed by the instant claims. Although Applicants have amended the claims to recite the term "tissue specific promoter," this limitation is so broad as to encompass the use of a promoter specific for any from of tissue in an organism. Therefore, the addition of this limitation to the claims does not provide further guidance to skilled artisan as to which "tissue specific promoter" to use in combination with truncated type IIA tau molecules for the production of a transgenic non-human animal as a model for Alzheimer's disease. There is no specific guidance in the specification as filed in this regard. Again, there is generic teaching for the production of a transgenic animal. However, again the skilled artisan given the specification as a guide, and what is known in the prior art, would have had to undertake undue experimentation to practice the full scope of the claimed invention.

5. Additionally, it is noted that with the exception of claim 40, claims 39, and 43-46 are not limited to any specific amino acid sequence structure, i.e. by "SEQ ID NO." Therefore, the exact structure of the constructs recited in the claims remains unclear, and the scope of the claims encompass any allelic or polymorphic variant form of these proteins. As stated in the prior Office Acton, though the recombinant technology for the generation of new mutant proteins is highly developed, the ability to determine *a priori* whether a mutation and/or deletion and/or insertion will generate a functional protein is not predictable. Since the relationship between a sequence of a peptide and its tertiary structure is not well understood and is not predictable, it would require undue

experimentation for one skilled in the art to determine alternative sequences of N- and C-terminally truncated tau protein molecules, such that transgenic animal expressing this truncated protein would produce an animal model suitable for isolating therapeutic candidates for the treatment of Alzheimer's disease.

6. Moreover, although Applicants have made reference to a variety of publications as evidence that a variety of animals are capable of exhibiting a neurofibrillary pathology. Again, contrary to Applicant's assertions, due to the unpredictability in the art in using transgenic animals as models for Alzheimer's disease, Applicants cannot substantiate a reasonable correlation between any non-human transgenic animal exhibiting neurofibrillary pathology producing activity and a model of Alzheimer's disease in a human. This unpredictability is due to the distinct phenotypes observed in closely related rodents such rats and mice in the expression of the same gene e.g., Amyloid Precursor Protein (APP; see Gotz et al. (2001)) and, conversely, the pleiotropic roles of the same gene e.g., the NF tangles associated with widely divergent neurodegenerative diseases in addition to Alzheimer's disease in terms of their pathologic mechanisms including supranuclear palsy, parkinsonism linked to chromosome 17, corticobasal degeneration, and others (Lewis et al. (2000)).

7. Due to the breadth of the claimed invention, the limited and prophetic guidance in the specification as filed, and the unpredictability associated with the production of a transgenic animal exhibiting a phenotype that correlates with risks factors associated with Alzheimer's disease, the skilled artisan would have to undertake undue experimentation to practice the full scope of the claimed invention.

Double Patenting

8. Claims 39-40 remain rejected and claims 43-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-21 of copending Application No. 10/521049. According to Applicants, a terminal disclaimer will be filed if the copending application issues as a US Patent. Also, Applicants stated that if the obvious type double patenting rejection remains as the only rejection of record, the examiner should withdraw the rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633